



PERMIT TO CONSTRUCT/OPERATE

This initial permit must be renewed ANNUALLY unless the equipment is moved, or changes ownership.
If the billing for the annual renewal fee (Rule 301.f) is not received by the expiration date, contact the District.

**Legal Owner
or Operator:**

ST. JUDE MEDICAL CRMD
15900 VALLEY VIEW CT
SYLMAR, CA 91392-9221

ID 103609

Equipment Location: 15900 VALLEY VIEW CT, SYLMAR, CA 91342

Equipment Description :

Ethylene Oxide Sterilizer, No. 2R, Getinge, Model No. GEE101420-1; 3' -3.4" W. x 4'-9.1" H x 6'-6.7" L., with a 100 KW Electric Steam Generator.

Conditions :

1. Operation of this equipment shall be conducted in accordance with all data and specifications submitted with the application under which this permit is issued unless otherwise noted below.
2. This equipment shall be properly maintained and kept in good operating condition at all times.
3. This equipment shall not be operated unless vented to the ETO control devices that are in compliance with SCAQMD Rule 1405 and have been issued a Permit to Construct or Operate by SCAQMD.
4. The total ethylene oxide (ETO) used in this facility shall not exceed 4,000 pounds in any one calendar year.
5. The total ethylene oxide (ETO) used in this facility shall not exceed 16 pounds in any one day.
6. A daily log indicating the date, the sterilization chamber identification number, the sterilization cycle start-up and completion time, the time of the day when the chamber is purged, and pounds of ETO used for each sterilization cycle shall be maintained for each ETO sterilization chamber.
7. The equipment and all the devices and components which are connected to this equipment shall be leak tested every six months using the latest CARB test method during conditions of maximum sterilant gas use.
8. There shall be no staging of sterilized products in uncontrolled areas of the plant. Any test or bio indicator removal shall be conducted in an enclosed location that is vented to an ETO control equipment.
9. The valves on ethylene oxide drums shall be completely closed when not in use. If closing of a drum valve cannot contain ETO, or if there is an indication of ETO leak from any other part of an ETO drum, the drum shall be immediately moved to area that is vented to an ETO control equipment.

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10. The operator shall comply with all requirements specified in the Ethylene Oxide Airborne Toxic Control Measure (ATCM) for Sterilizers and Aerators, Parts 1 and 2 under Title 17 of California Code of Regulations, Sections 93108 and 93108.5 (17 CCR, Sections 93108 and 93108.5).
11. The operator shall comply with all requirements specified in the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations under Code of Federal Regulations, Title 40, Part 63 subpart O (40CFR 63, subpart O).
12. The sterilizing chemical used in this equipment shall not contain any toxic air contaminants identified in Rule 1401, Table I, with an effective date of October 7, 2016 or earlier, except for ethylene oxide (CAS no. 75-21-8).
13. Records shall be maintained to demonstrate compliance with conditions 4, 5, 6, and 7. The records shall be kept for at least two years and made available to SCAQMD personnel upon request.

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South Coast Air Quality Management District
21865 Copley Drive, Diamond Bar, CA 91765-4178

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Permit No.
R-G48221
A/N 594738

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**THIS PERMIT TO CONSTRUCT/OPERATE R-G48221 SUPERSEDES PERMIT TO CONSTRUCT/OPERATE
G48221 ISSUED 9/8/2017**

NOTICE

In accordance with Rule 206, this Permit to Operate or copy shall be posted on or within 8 meters of the equipment.

This permit does not authorize the emission of air contaminants in excess of those allowed by Division 26 of the Health and Safety Code of the State of California or the applicable Rules and Regulations of the South Coast Air Quality Management District (SCAQMD). This permit cannot be considered as permission to violate existing laws, ordinances, regulations or statutes of other government agencies.

Executive Officer

A blue ink signature of Laki Tisopoulos is written over the printed name.

BY LAKI TISOPULOS,
1/3/2018

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